NAIMA
NORTH AMERICAN INSULATION MANUFACTURERS ASSOCIATION

VIA OVERNIGHT MAIL AND E-MAIL

September 28, 2009

Dr. Ruth M. Lunn
Director
RoC Center, National Toxicology Program
National Institute of Environmental Health Sciences
530 Davis Drive, Room 2006
Durham, NC 27713

RE: NAIMA's Comments on Expert Panel Recommendations on Glass Wool Fibers – 74 Fed. Reg. 40,598 (August 12, 2009)

Dear Dr. Lunn:

INTRODUCTION

The North American Insulation Manufacturers Association ("NAIMA") appreciates the opportunity to submit comments on the recommendations from the Expert Panel on the listing status for glass wool fibers in the 12th Report on Carcinogens ("RoC") and the scientific justification for the recommendations. 74 Fed. Reg. 40,598 (August 12, 2009).

NAIMA is an association representing the manufacturers of glass wool insulation in the United States and throughout North America. On January 28, 2002, NAIMA filed with the National Toxicology Program ("NTP") a petition to delist glass wool (respirable size) from the RoC. NAIMA submitted written and oral comments on the background documents addressing the proposed delisting of glass wool. NAIMA did not comment directly on the listing of special purpose fibers, but did address the basis for distinguishing glass wool and special purpose fibers.

In response to the Expert Panel's recommendations, NAIMA's comments focus on the recommended delisting of glass wool fibers and the scientific justification for that recommendation. In addition, NAIMA also responds to NTP's specific request for comments on the separation of glass wool fibers into two categories for purposes of listing in the RoC and on the set of physical characteristics that the Expert Panel used to classify the fibers into two categories.

44 Canal Center Plaza ▪ Suite 310 ▪ Alexandria, Virginia 22314 ▪ Tel: (703) 684-0084 ▪ Fax: (703) 684-0427

RECOMMENDATION AND SCIENTIFIC JUSTIFICATION

The Expert Panel's recommendation to delist glass wool is consistent with the findings of the International Agency for Research on Cancer ("IARC"),[1] the Agency for Toxic Substances and Disease Registry's ("ATSDR") Toxicological Profile for Synthetic Vitreous Fibers,[2] the U.S. National Academy of Sciences ("NAS"),[3] and scientific bodies in the United Kingdom,[4] Canada,[5] the Netherlands,[6] Australia and New Zealand,[7] and others.[8] Most of these reviews and cancer classification analyses are described in NAIMA's comments filed with NTP on May 22, 2009.[9] Thus, adoption by the Department of Health and Human Services of the Expert Panel's approach and recommendation would bring the United States' cancer classification of glass wool into harmony with the international scientific community.

As discussed more fully below, the Expert Panel's recommendation is supported by the extensive scientific database on glass wool. The epidemiological data from the United States cohort and the European cohort, a very large and high-quality database, did not show a causal relationship between manufacturing workers' exposure to glass wool and cancer. Thus, the Expert Panel correctly concluded that "there is insufficient evidence for the carcinogenicity of glass wool in humans." In both its original 1988 classification as well as in its 2001 re-evaluation contained in Monograph 81 (2002), IARC similarly determined that the human data were "inadequate." Dr. Gary Marsh's comments to the Expert Panel discussed the basis for IARC's conclusion and further analyzed the post-2001 IARC epidemiology, concluding that "the collective epidemiological and other scientific evidence published since the 2001 IARC review revealed that IARC's 2001 decision to downgrade glass insulation wool from Group 2B to Group 3 remains valid. . ."[10]

The Expert Panel concluded that animal data showed only limited evidence of carcinogenicity in animals.[11] The Expert Panel considered both inhalation and intraperitoneal routes of exposure,

---

[1] International Agency for Research on Cancer, *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Man-Made Vitreous Fibres*, Vol. 81 (Lyon, France: WHO/IARC, 2002); www.iarc.fr/ENG/Press_Releases/archives/pr137a.html.

[2] *Toxicological Profile for Synthetic Vitreous Fibers* (U.S. Department of Health and Human Services, Public Health Services, Agency for Toxic Substances and Disease Registry), September 2004.

[3] NRC Subcommittee on Manufactured Vitreous Fibers. 2000. *Review of the U.S. Navy's Exposure Standard for Manufactured Vitreous Fibers*. National Academy of Sciences, National Research Council, Washington, D.C.: National Academy Press.

[4] United Kingdom Department of Health, *1994 Annual Reports on the Committees on Toxicity, Mutagenicity, Carcinogenicity of the Chemicals in Food, Consumer Products and the Environment* (1995).

[5] Government of Canada, *Mineral Fibres (Man-Made Vitreous Fibres)* (1993).

[6] Netherlands Committee of the Health Councils, *Man Made Mineral Fibers* (Sept. 8, 1995).

[7] Insulation Wools Research Advisory Board, Sydney, Australia (Oct. 1995).

[8] International Programme on Chemical Safety, WHO, *Environmental Health Criteria 77, Man-Made Mineral Fibres* (1988).

[9] Comments of the North American Insulation Manufacturers Association, http://ntp.niehs.nih.gov/ntp/roc/twelfth/2009/june/Mentzer20090522.pdf?bcsi_scan_7909DC0819E730E8=0&bcsi_scan_filename=Mentzer20090522.pdf (May 22, 2009).

[10] Comments on National Toxicology Program Draft Background Document on Glass Wool Fibers, June 8-10, 2009, Gary M. Marsh, p. 27 (http://ntp.niehs.nih.gov/ntp/roc/twelfth/2009/june/Marsh20090522.pdf).

[11] With respect to the Expert Panel's comments on the Mitchell-Moorman study, it is important to note the 2001 IARC Working Group's characterization of that study: "[The working group noted that the physical dimensions

but acknowledged that inhalation studies were more relevant for humans. The Expert Panel's conclusion that inhalation studies were more probative of potential human hazard than injection studies is strongly supported by other authoritative reviews. For example, the National Research Council ("NRC") Report states:

> It appears reasonable to conclude that extrapolations from animal toxicity data to humans for MVF can best be made when experimental animals are exposed to fibers via inhalation.[12]

Regarding the issue of intracavitary injection studies, the same NRC report concludes:

> The subcommittee agrees with a WHO scientific panel's conclusion that the intraperitoneal model should not be used for quantitative risk assessment or for comparing relative hazards posed by different fibers (WHO 1992).[13]

In 1996, a workshop report sponsored by EPA in collaboration with NIEHS, NIOSH, and OSHA,[14] similarly concluded:

> After extensive discussion and debate of the workshop issues, the general consensus of the expert panel is that chronic inhalation studies of fibers in the rat are the most appropriate tests for predicting inhalation hazard and risk of fibers to humans.[15]

Based on the factors discussed above, the Expert Panel's decision to delist glass wool from the RoC is justified by the science and is consistent with the conclusions, findings, and classifications of a wide and diverse group of international scientific and authoritative bodies.

SEPARATION OF GLASS WOOL INTO TWO CATEGORIES

The Expert Panel's recommendation and analysis separated glass wool fibers into two distinct categories. The Expert Panel's decision reflects a thorough and appropriate analysis given that there were two separate nominations before it – a petition to delist glass wool (respirable size) and a nomination to list special purpose fibers as "reasonably anticipated." More importantly,

---

(length and diameter) of the fibres and the numbers of fibres in the exposure aerosol and the lungs were not characterized and the lung burden was not given.] No lung fibrosis, lung cancer or mesotheliomas were observed in the rats exposed to fibres. The incidence of mononuclear-cell leukaemia was statistically elevated in the groups exposed to fibres when compared with the air control group. However, this tumour type is observed at relatively high incidences (22% in the current study) in ageing Fischer 344 rats." International Agency for Research on Cancer, *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Man-Made Vitreous Fibres*, Vol. 81 (Lyon, France: WHO/IARC, 2002), p. 189.

[12] NRC Subcommittee on Manufactured Vitreous Fibers. 2000. *Review of the U.S. Navy's Exposure Standard for Manufactured Vitreous Fibers*. National Academy of Sciences, National Research Council, Washington, D.C.: National Academy Press, p. 39.

[13] *Ibid*.

[14] Vu, V., Barrett, J.C., Roycroft, J., Schuman, L., Dankovic, D., Baron, P., Martonen, T., Pepelko, W., and Lai, D., Workshop Report, "Chronic Inhalation Toxicity and Carcinogenicity Testing of Respirable Fibrous Particles," *Regulatory Toxicology and Pharmacology* 24 (1996) 202-212.

[15] *Ibid*., p. 202.

international and U.S. authoritative bodies have similarly separated glass wool into two distinct categories based on distinct hazard potential. Over the past twenty-plus years, these authoritative bodies have recognized that insulation glass wools and special purpose fibers can, and should be, distinguished. NAIMA's May 22, 2009 comments to NTP (enclosed) provided a detailed summary of how various organizations, including the World Health Organization ("WHO"), the American Conference of Governmental Industrial Hygienists ("ACGIH"), the International Labour Organization ("ILO"), IARC, and ATSDR, had separated glass wool into two separate categories. Thus, the Expert Panel's careful conclusions describing two categories of glass wool are consistent with the international scientific community's characterization of glass wool and the extensive data.

PHYSICAL CHARACTERISTICS

The Expert Panel utilized physical characteristics of the two separate glass wools to distinguish them. Specifically, the Expert Panel recommended that glass wools generally be delisted save for glass fibers of concern defined as follows: "longer, thinner, less soluble fibers (for example, > 15 μm length with a kdis of < 100 ng/cm^2/h)."

In distinguishing these fibers, the Expert Panel relied upon the same physical characteristics identified by the various authoritative bodies referenced above. The Expert Panel, however, provided more detailed analysis, greater clarity, and further distinction than had previously been achieved by any of the other authoritative bodies. The physical characteristics used by the Expert Panel to classify these fibers into two categories will be useful to the regulatory community and to manufacturers. NAIMA and its members strongly support the Expert Panel's use of physical characteristics to define special purpose fibers.

CONCLUSION

The Expert Panel's recommendation to delist insulation glass wool is consistent with the extensive published scientific research and the conclusions reached by the NAS in 2000, IARC in 2002, and ATSDR in 2004. The extensive published research demonstrates, as confirmed by NAS, IARC, and ATSDR, that insulation glass wool "does not meet either the criteria for human or animal evidence that are required for listing in the RoC."

Sincerely,

Angus E. Crane

Angus E. Crane
Executive Vice President

Enclosure